UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,284	02/09/2004	Yuan Y. Lee	USP2270A-YYL	1138

30265 7590 07/13/2007

RAYMOND Y. CHAN
108 N. YNEZ AVE., SUITE 128
MONTEREY PARK, CA 91754

EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,284	LEE, YUAN Y.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-43* is/are pending in the application.

4a) Of the above claim(s) *5-35 and 40-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/8/07 has been entered.

Claims 5-43 are pending in the application.

Claims 5-35 and 40-43 remain withdrawn from the merits as they are directed toward a non-elected invention.

Claims 36-39 were examined on their merits.

Claim Rejections - 35 USC § 103

Claims 36-39 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (US 5,741,491) in view of Yang et al. (2003).

Applicant's arguments were fully considered, but not found persuasive.

Applicant generally argues considerations under the 35 USC 103(a) statute..."A patent may not be obtained...not identically...if the differences between the subject matter as a whole would have been obvious....the disclosure of the prior art and the invention are not identical and there are one or more differences between the subject matter sought to be patented....differences...as a whole and the prior art are obvious at the time the invention was made...the differences between the subject matter sought to be patent [*sic*, patented] as a whole of the Instant Invention and Jones..which is qualified... (p. 2, Remarks).

Applicant argues that the reasoning for the Examiner's basis in setting forth the Instant rejection "...is clearly not a proper basis for combining references in making out an obviousness rejection of the present claims. Rather the invention must be considered as a whole and there must be something in the reference that suggests the combination or the modification"...(Applicant additionally *cites Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick, In re Gordon* and *In re Laskowski*)...In the present case, there is no such suggestion" (p. 3, Remarks).

However, the Examiner respectfully disagrees. As keenly pointed out in the previous Office Action, the references do not need to explicitly state a motivation for combining the references. The invention was considered as a whole, and since each herbal medicine was already known in the art for treating diabetes, one would have been motivated to combine the herbal medications to provide for an additive effect. The Examiner has already cited case law in support of the outstanding rejection; namely; *In re Sussman* and *In re Kerkhoven*, which cases make clear that the combination of elements which were known for the same purpose in the art is *prima facie* obvious. What is also clear in patent law is that the motivation for combining the elements can be entirely different from the intent of the Inventor .

Applicant argues "In oriental medicine, all herbal medicine dose is a combination of known herbs in specific proportions for treatment of known or unknown sickness. According to the Examiner's allegation, all new inventions in combination of known herbs for new diseases are not patentable, no matter whether there is any suggestion of combining these known herbs in specific proportion for such disease, merely because the combined herbs were known in the art" (p. 3, Remarks). However, the Examiner respectfully disagrees with Applicant on this points and indicates that Applicant is misinterpreting the Examiner's statements, and over generalizing the nature of the outstanding rejection. The Examiner did not simply state that the combination of herbals in the claims were obvious because they were 'known in the art'; on the

contrary, both herbs are known in the art for treating the *same condition*. The Examiner cannot find the relevance in Applicant's arguments regarding oriental medicine because the claimed herbs were not just simply found in a combination of traditional Chinese medicine cocktails for treatment of diabetes, but the two claimed herbs are known in the art ***alone*** for the treatment of diabetes. Combinations of herbal medicines are well known in the art and novel combinations are routinely patented. However, it remains deemed that the combination of herbals as Instantly claimed is prima facie obvious over the prior art references, in that the teachings of the prior art references as a whole make obvious the entirety of the claimed invention.

Applicant argues that "Jones discloses six tables...glucose level improvement...does not occur in all subject groups. For some subject groups the glucose level is even 'unchanged'. All of the tables show that the outcomes of the claimed composition in Jones patent are obtained after ***FOUR WEEKS*** treatment period" (p. 4, Remarks, emphasis in original Remarks). Applicant additionally argues that "...the use of Toona sinensis leaf extracts for treatment of diabetes is limited" and concludes that "...Jones and Yang et al. do not in way teach, suggest, or motivate the use of a combination of Heracleum lanatum and Toona sinensis leaf extract to significantly enhance the performance of diabetes treatment, and in particular, minimization of the time required to achieve significant reduction of glucose level". Applicant further states that the Instant specification shows a reduction of glucose level by at least 20% after 30 days of treatment which Applicant considers an

"...***unexpectedly good*** performance and is more than a mere additive effect..." (p. 4, Remarks, emphasis in original remarks). The Examiner concedes that Jones disclosed treatment for four weeks. The Instant specification teaches that the one subject tested, was tested for 30 days. While Applicant stresses the fact that four weeks of testing were required by Jones, *30 days is approximately four weeks* and therefore does not make much difference. Further, while the Specification shows approximately 20% reduction, many of the subjects in the Jones study decreased their glucose levels by 20% or more (see Table 1). While Applicant argues that 'glucose level improvement does not occur in all subject groups', this argument is without merit in that it is well known in the art of science that data is gathered and quantitated based on averages in a group. It appears that Applicant is merely attempting to negate the data of Jones by pointing out one subject in Table 1 which was non-responsive to the *H.lanatum* which is an incorrect analysis of the data and possibly the non-responsive individuals present in the placebo group. It is demonstratively clear from Table 1 of Jones that *H.lanatum* lowers blood glucose levels, and in some instances, *greater than what is shown in the Instant specification for the combination* of known diabetes herbal medicines of *H.lanatum* and *T. sinensis*. Further, some of the Tables of Jones are directed toward the placebo groups whereby a positive result would not be expected which Applicant does not address. Therefore, Applicant's arguments concerning an 'unexpectedly good performance' of the combination of herbs is not convincing.

Where Applicant argues that "..it is clear that the use of *Toona sinensis* leaf extracts for treatment of diabetes is limited" is not understood. It is clear that Yang et al. demonstrated the glucose-uptake ability of *Toona sinensis* according to the Abstract alone. The addition of cyclohexamide to the adipocyte cell culture was merely carried out in order to elucidate the mechanism by which *Toona sinensis* functions to enhance glucose uptake and does not indicate any inability of *T.sinensis* to enhance glucose uptake under normal cellular conditions.

Applicant concludes by stating that "...Jones and yang et al. did not specifically teach, suggest or motivate a combination of Heracleum lanatum and Toona sinensis leaf extract for the treatment of diabetes". The Examiner respectfully disagrees and maintains the outstanding rejection for the reasons set forth keenly in the previous Office Action as well as *supra.*

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

This is an RCE of applicant's earlier Application No. 10/775,284. All claims are drawn to the same invention claimed in the earlier application and could have been

finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia Leith/
Patricia Leith
Primary Examiner
Art Unit 1655

July 8, 2007